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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,044	03/16/2005	Petrus Besselink	BES 0009 PA	2774

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EXAMINER	
HOUSTON, ELIZABETH	
ART UNIT	**PAPER NUMBER**
3731	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,044	BESSELINK, PETRUS	
	Examiner	Art Unit	
	ELIZABETH HOUSTON	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 January 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-74* is/are pending in the application.

4a) Of the above claim(s) *7,11,12,14,22-40,43-47,49,50,53,54 and 60-74* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-10,13,15-21,41,42,48,51,52 and 55-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-5, 8, 9, 13, 15, 18-21, 41, 42, 48, 51, 52 and 55-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsugita (US 6,371,064) in view of Gianotti (US 5,836,962).

3. Regarding claim 1 and 48, Tsugita discloses a medical device configured to be disposed within a body lumen, said device comprising a mesh of braided fibers (25).

4. Tsugita does not disclose that the fibers are reinforcement fibers coupled to a membrane to form a composite structure. However Gianotti discloses a mesh of braided fibers similar to that of Tsugita, where each fiber is a composite structure (2) (C1:L52-53) formed from reinforcement fibers (4) coupled to a membrane (5). Gianotti discusses the advantages of using a composite fiber to increase biocompatibility without compromising necessary stiffness (C1:L29-49) as well as providing the ability to incorporate contrast medium for better positioning the device (C3:L58-62) and the ability to provide drug delivery (C4:L31-65). It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate these composite fibers in place

of the fibers used in the filter of Tsugita to achieve the advantages taught by Gianotti. As such, the combination would result in the fibers of Tsugita (25) becoming fibers coupled to a membrane to form the composite structure.

5. Additionally modified Tsugita discloses: Claim 2 and 48: further comprising a frame (22) attached to the fibers (mesh 25) to hold the fibers in a desired shape, said frame comprising a proximal end (111) and a distal end (112); Claim 3 and 48: further comprising an elongated member (30) configured to transport said device to an appropriate location in said body lumen; Claim 4 and 52: wherein said elongated member comprises a guide wire (30) attached to at least one of said frame or said composite structure (Fig. 4c); Claim 5: wherein said proximal end of said frame is remote from said membrane (Fig. 4c); Claim 8: further comprising a plurality of slide rings (111, 112), each of said slide rings connected to opposing ends of said device such that said slide rings are responsive to displacement forces imparted thereto by said guide wire; Claim 9: wherein the reinforcement fibers are directly attached to one of said slide rings and said distal end of said frame; Claim 13: wherein said frame is configured to allow said guide wire to move freely in axial, radial, tangential and rotational directions within said frame when said frame is in an expanded state without influencing the position and shape of said device (C2:L58-63); Claim 15: wherein said frame has elongated struts (181) that define attachment points at said proximal end to facilitate connection of said frame to said guide wire (Fig. 16a); Claim 18: further comprising a hollow tube (10)advance able into a region at least partially enclosed by said composite structure when said composite structure is in an open state; Claim 19:

said guide wire is configured to fit within said hollow tube (C10:L40-55); Claim 20: said tube is configured to perform at least one of a suction, flushing, inspection, measuring, clot-breaking, and retrieval device introduction functions while said tube is advanced into said at least partially enclosed region (angioplasty C10:L45); Claim 21: said hollow tube is dimensioned to serve as a removal sheath for said device; Claim 41: wherein said composite structure is a filter that is expandable into an expanded state, said filter comprising a substantially closed distal end and an open proximal end such that said filter tapers from said proximal end to said distal end (Fig. 16a); Claim 42: further comprising a reservoir (defined by membrane 22) in said filter that extends from said distal end, said reservoir defining a debris storage space; Claim 51: and a plurality of stops (167, 168; C14:L53-57) affixed to said guide wire such that upon contact between one of said stops and one of said first or second rings due to movement of said elongated member, said device moves either into or out of said body lumen.

6. Regarding claim 55: modified Tsugita teaches first coupled to the membrane and second fibers coupled to the frame (even though all fibers would be the same, some can be chosen to be in the first group and some chosen to be in the second group) and a guidewire (30) coupled to the frame (22) and the composite structure (25) (Fig. 4c); Claim 56: the first fibers are reinforcement fibers; Claim 57: the frame is attached to the composite structure through the reinforcement fibers; Claim 58: the material making up the first and second fibers is the same; And Claim 59: the reinforcement fibers are discontinuous (since there are multiple fibers) and dispersed throughout said membrane (Fig. 3).

7. Claims 6, 10, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsugita in view of Gianotti as applied to claims above, and further in view of Daniel (US 5,814,064).

8. Tsugita modified by Gianotti does not disclose that which is taught by Daniel. Daniel teaches a filter device that comprises pulling fibers (222) connecting said proximal end of said frame to said guide wire (indirectly) to enable said device to be retracted into a removal sheath by a pulling force on said guide wire in order to retrieve said device from said body lumen (C9:L64-C10:L2). The fibers are connected to attachment points by means of attachment holes (220) disposed therein.

9. As to claim 17, Daniel teaches a fiber connected to attachment points but is silent as to how the fibers are attached. The claimed phrase “by gluing or welding” is being treated as a Product by Process limitation that is that is the fibers are attached by the process of gluing or welding. As set forth in the MPEP 2113, "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (See MPEP § 2113). Examiner will thus evaluate the product claims without giving much weight to the method of its manufacture.

Response to Arguments

10. Applicant's arguments filed 01/05/10 have been fully considered and are not persuasive.

11. Applicant states that the composite structure of Gianotti is readily distinguished from the claimed device. However the claims require a membrane and reinforcement fibers coupled to the membrane to form a composite structure. This is exactly what is taught by Gianotti as described in the rejection above. While the structure of Gianotti may be readily distinguished from the invention described in the application, it is not readily distinguished from the claimed invention. It is apparent that the claimed structure needs to be more clearly defined to overcome the structure of the prior art. For example applicant describes how the instant invention has a composite structure with extreme flexibility and elasticity in bending along with high strength and prevention of crack propagation. Again none of this is found within the scope of the claims.

12. Applicant argues that the combination of Gianotti and Tsugita is improper because the two references teach away from each other. Applicant specifically states that the high rigidity composite of Gianotti would deprive Tsugita the flexibility needed to achieve blood perfusion capabilities. However, applicant provides no support for this statement. It has been found that the arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding

unexpected results, commercial success, solution of a long-felt need, *inoperability of the prior art*, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant. See MPEP § 2145 generally for case law pertinent to the consideration of applicant's rebuttal arguments.

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

14. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH HOUSTON whose telephone number is (571)272-7134. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. H./
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
3/23/10